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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,543	12/20/1999	SHUJI HINUMA	2472US0P	2478

23115 7590 12/03/2003

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC  
INTELLECTUAL PROPERTY DEPARTMENT  
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LINCOLNSHIRE, IL 60069

EXAMINER

MITRA, RITA

ART UNIT PAPER NUMBER

1653

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/446,543	HINUMA ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>0923</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                 |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

In view of the amendment filed on August 7, 2003, prosecution is hereby reopened.

#### ***Status of the Claims***

Applicants' amendment and response to office action dated May 7, 2003, filed on August 7, 2003 is acknowledged and has been entered. Claims 20-21 and 24-35 have been cancelled. Claims 22 and 23 have been amended. Therefore, claims 22 and 23 are currently pending and are under examination.

#### ***Response to Remarks and Arguments***

#### **Withdrawal of Objection/Rejections**

The objection to Specification is withdrawn in view of Applicants' amendment to specification and claims by assigning a SEQ ID NO: 5 to 19P2-L31.

The rejection of claims 20-21 and 24-35 under 35 U.S.C. § 112, first paragraph is moot in view of Applicants' cancellation of the claims.

The rejection of claims 20-21 and 24-35 under 35 U.S.C. § 112, second paragraph is moot in view of Applicants' cancellation of the claims.

The rejection of claims 20-23 under 35 U.S.C. § 102(a) and 102(e) as being unpatentable over Hinuma et al. (US 6,228,984) is moot in view of Applicants' cancellation of claims 20 and 21. The rejection of claims 22 and 23 is withdrawn in view of Applicants' amendment to claims.

The rejection of claims 20-23 under 35 U.S.C. § 102(a) as being unpatentable over Hinuma et al. (Nature, vol 393, No. 6682, pp272-276, 21 May 1998) is moot in view of Applicants' cancellation of claims 20 and 21. The rejection of claims 22 and 23 is withdrawn in view of Applicants' amendment to claims.

#### **Rejections under 35 U.S.C. § 112, Second Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 22 and 23 stand/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 23 stand rejected as being indefinite because they lack essential steps as claimed in the methods. The omitted steps are: the site and method of administration, the therapeutically effective amount of the agent and a step whereby the desired outcome using the claimed polypeptide can be determined. Applicants have not addressed 112, second paragraph rejection in the response of office action dated May 7, 2003.

#### **New grounds of Rejection**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 22 and 23 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Hinuma et al. (US Patent 6, 228,984, Issued May 8, 2001; 102(e) date: February 6, 1997). Hinuma et al. teach a novel ligand polypeptide for the G protein-coupled receptor protein, having an amino acid sequence set forth in SEQ ID NO: 73 or its substantial equivalent thereto, or its

amide or ester or salt thereof. The polypeptide has an amino acid sequence of SEQ ID NO: 5 (US '984 technical field col. 1; col. 2 lines 36-47 and claims 1, 2). The reference teaches a pharmaceutical composition containing the polypeptide ( pituitary function modulator, '984, col. 3, lines 15-17) and has 100% sequence identity to SEQ ID NO: 5 (see alignment result, Database: Issued\_Patents\_AA, AC NO: US-08-776-971-5) (claims 22, 23). Hinuma's polypeptide comprising SEQ ID NO: 5 is considered for the ligand polypeptide having an amino acid sequence of SEQ ID NO: 5 for the use in a method for promoting prolactin secretion, (claims 22-23). Therefore, claims 22-23 of the instant application are anticipated by Hinuma et al.

#### *Conclusion*


No claim is allowed.

#### *Inquiries*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.  
November 25, 2003

  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
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